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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,439	06/07/2002	Toshio Miyata	2605/103	3663

2101 7590 09/29/2004  
BROMBERG & SUNSTEIN LLP  
125 SUMMER STREET  
BOSTON, MA 02110-1618

EXAMINER
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ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/069,439

**Applicant(s)**

MIYATA, TOSHIO

**Examiner**

Janet L. Andres

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 15-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/02, 5/02, 3/03</u> .  | 6) <input checked="" type="checkbox"/> Other: <u>sequence alignments</u> .  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I, polynucleotides and the encoded polypeptides, in the reply filed on 6 July 2004 is acknowledged. Claims 1-21 are pending in this application. Claims 15-21 are withdrawn from consideration as being drawn to a non-elected invention.

### ***Specification***

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on p. 30, lines 6-7. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. In addition, there is a sequence on p. 8, line 31, that requires a sequence identifier.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6, 9, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kloeker et al., Journal of Biological Chemistry, 1999, vol. 274(9), pp. 5339-5347.

Kloeker et al. teach a polynucleotide that is 94.6% identical to Applicant's SEQ ID NO: 1 and is 98% identical to polynucleotides encoding SEQ ID NO: 2. See attached alignments. Thus, Kloeker et al. teaches a polynucleotide that encodes a polypeptide in which one or more amino acids are substituted, deleted, inserted, or added and that is functionally equivalent to the

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polypeptide of SEQ ID NO: 2. Vectors, transformants, oligonucleotides, and antisense molecules are taught on p. 5341, in column 2. The intended use of claim 9 does not alter the nature of the invention itself, which is an oligonucleotide anticipated by those taught by Kloecker et al.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 7-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection and synthesis of MEG-1 using oligonucleotides from regions non-identical to serine/threonine phosphatase 4, does not reasonably provide enablement for detection or synthesis using all oligonucleotides derived from SEQ ID NO: 1. The specification further does not provide enablement for detection of mesangial nephritis in cells other than mesangial cells, or by detection of sequences not identical to SEQ ID NO: 1 or the encoded protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman*, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

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Claims 7 and 8 are drawn to detection or synthesis of SEQ ID NO: 1. As stated above, Kloeker et al. teach a sequence nearly identical to Applicant's polynucleotide. Kloeker et al. further teach detection of this polynucleotide using oligonucleotides. Thus, oligonucleotides from the identical regions of the sequences would hybridize with the polynucleotide of Kloeker as well as Applicant's disclosed sequence. No means of differentiation is provide in the specification or in the claims. Without further direction in the form of additional method steps or limitations as to the oligonucleotides used in Applicant's claimed methods, it would thus require undue experimentation for the artisan to practice the invention as broadly claimed.

Claims 9-12 are drawn to methods and reagents for detecting mesangial cels and mesangial nephritis. These could not be detected by detection of all of the proteins and polynucleotides within the scope of the claims, since there is no guidance to indicate that the phosphatase taught by the prior art or other molecules not identical to the MEG-1 have similar expression characteristics. Further, detection using oligonucleotides from the regions identical to the prior art, or detection of fragments of protein identical to the prior art would not distinguish between MEG-1 and related molecules.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1(c) is indefinite because polynucleotides do not comprise amino acids. Claim 1(c) is also indefinite in its limitations. Because there is no restriction on the number of changes

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that can be made, the artisan would be unable to determine what molecules Applicant intended to claim. This section, as well as section (d), are further indefinite in the recitation of "biological activity". No particular activity is defined in the specification; thus the artisan would not know what activities were encompassed. Section (d) is additionally indefinite because no hybridization conditions are required; "stringent conditions" are not defined in the specification.

Claim 12 is indefinite because SEQ ID NO: 1 is not an mRNA and because it recites "selected from the nucleotide sequence of SEQ ID NO: 1" with no other option.

Claims 12 and 13 are indefinite because it is unclear as to whether the "indicator" is to be detected or is the detecting molecule. Presumably a protein or fragment thereof cannot be used to detect gene expression but clarification is required.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.  
24 September 2004

  
**JANET ANDRES**  
**PRIMARY EXAMINER**

AF111106  
 LOCUS AF111106 3878 bp mRNA linear PRI 03-MAR-1999  
 DEFINITION Homo sapiens protein serine/threonine phosphatase 4 regulatory subunit 1 (PP4R1) mRNA, complete cds.  
 ACCESSION AF111106  
 VERSION AF111106.1 GI:4191593  
 KEYWORDS .  
 SOURCE Homo sapiens (human)  
 ORGANISM Homo sapiens  
 Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.  
 REFERENCE 1 (bases 1 to 3878)  
 AUTHORS Kloeker, S. and Wadzinski, B.E.  
 TITLE Purification and identification of a novel subunit of protein serine/threonine phosphatase 4  
 JOURNAL J. Biol. Chem. 274 (9), 5339-5347 (1999)  
 MEDLINE 99150310  
 PUBMED 10026142  
 REFERENCE 2 (bases 1 to 3878)  
 AUTHORS Kloeker, S. and Wadzinski, B.E.  
 TITLE Direct Submission  
 JOURNAL Submitted (04-DEC-1998) Pharmacology, Vanderbilt University, 23rd Ave South & Pierce, Nashville, TN 37232-6600, USA  
 FEATURES  
 source Location/Qualifiers  
 1. .3878  
 /organism="Homo sapiens"  
 /mol\_type="mRNA"  
 /db\_xref="dbEST:AA171828"  
 /db\_xref="taxon:9606"  
 /tissue\_type="neuroepithelium"  
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 /gene="PP4R1"  
 CDS 94. .2895  
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 /db\_xref="GI:4191594"  
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ORIGIN





Qy	904	ACTTTTTATTAATTTGATCAGTGATCCTTCACGTTGGGTTCGCCAAGCAGCTTTTCAGTC	963
Db	924	ACTTTTTATTAATTTGATCAGTGATCCTTCACGTTGGGTTCGCCAAGCAGCTTTTCAGTC	983
Qy	964	TCTGGGACCTTTCATATCTACTTTTGCTAATCCATCTAGCTCAGGCCAGTATTTTAAAGA	1023
Db	984	TCTGGGACCTTTCATATCTACTTTTGCTAATCCATCTAGCTCAGGCCAGTATTTTAAAGA	1043
Qy	1024	AGAAAGCAAAAGTTTCTAGAAGAGATGTCTAGTAGAAAAACAAAATAGGACCAGAGATCAAGA	1083
Db	1044	AGAAAGCAAAAGTTTCTAGAAGAGATGTCTAGTAGAAAAACAAAATAGGACCAGAGATCAAGA	1103
Qy	1084	AGCCCCAGAGGATGTACAAGTCAGGCCAGAGGATACTCCTTCAGATCTCAGTGTTAGTAA	1143
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Qy	1144	TTCCAGTGTCTACTGGAAAACACGATGGAAGACCATGCTGCTGAGGCATCCGGGAAGCC	1203
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Qy	1324	ACGACCAGAGGTTGGCACCCTTCAAGATTTCAGCTCTCTTAGATCAGGAATTGTATAA	1383
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Qy	1384	CTCCTTCCATTTCTGGAGGACTCCTCTTCTGAAATAGATCTAGACATAGAGCTTGAACA	1443
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Qy	1504	CAGTTCTCCAAACATCACCATGGCCACCAGAAAGGAACTGGAAGAAATGATAGAAAATCT	1563
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Qy	1684	GCAAGATGAACTGGATATAAATGAGCTACCAAATTGTAAAATAAATCAAGAAGATTCTGT	1743
Db	1704	GCAAGATGAACTGGATATAAATGAGCTACCAAATTGTAAAATAAATCAAGAAGATTCTGT	1763
Qy	1744	GCCTTTAATCAGCGATGCTGTTGAGAATATGGACTCCACTCTTCACTATATTCACAACGA	1803

Db	1764	GCCTTTAATCAGCGATGCTGTTGAGAATATGGACTCCACTCTTCACTATATTACAGCGA	1823
Qy	1804	TTCAGACTTGAGCAACAATAGCAGTTTTAGCCCTGATGAGGAAAGGAGAACTAAAGTACA	1863
Db	1824	TTCAGACTTGAGCAACAATAGCAGTTTTAGCCCTGATGAGGAAAGGAGAACTAAAGTACA	1883
Qy	1864	AGATGTTGTACCTCAGGCGTTGTTAGATCAGTATTTATCTATGACTGACCCTTCTCGTGC	1923
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Qy	1924	ACAGACGGTTGACACTGAAATTGCTAAGCACTGTGCATATAGCCTCCCTGGTGTGGCCTT	1983
Db	1944	ACAGACGGTTGACACTGAAATTGCTAAGCACTGTGCATATAGCCTCCCTGGTGTGGCCTT	2003
Qy	1984	GACACTCGGAAGACAGAATTGGCACTGCCTGAGAGAGACGTATGAGACTCTGGCCTCAGA	2043
Db	2004	GACACTCGGAAGACAGAATTGGCACTGCCTGAGAGAGACGTATGAGACTCTGGCCTCAGA	2063
Qy	2044	CATGCAGTGGAAGTTTCGACGAACTCTAGCATTCTCCATCCACGAGCTTGCAGTTATTCT	2103
Db	2064	CATGCAGTGGAAGTTTCGACGAACTCTAGCATTCTCCATCCACGAGCTTGCAGTTATTCT	2123
Qy	2104	TGGAGATCAATTGACAGCTGCAGATCTGGTTCCAATTTTTAATGGATTTTTAAAGACCT	2163
Db	2124	TGGAGATCAATTGACAGCTGCAGATCTGGTTCCAATTTTTAATGGATTTTTAAAGACCT	2183
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Qy	2224	TGACAAAAGAAGAGAATATCTTTATCAACTTCAGGAGTTTTTGGTGACAGATAATAGTAG	2283
Db	2244	TGACAAAAGAAGAGAATATCTTTATCAACTTCAGGAGTTTTTGGTGACAGATAATAGTAG	2303
Qy	2284	AAATTGGCGGTTTCGAGCTGAACTGGCTGAACAGCTGATTTTACTTCTAGAGTTATATAG	2343
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Qy	2344	TCCCAGAGATGTTTATGACTATTTACGTCCCATTGCTCTGAATCTGTGTGCAGACAAAGT	2403
Db	2364	TCCCAGAGATGTTTATGACTATTTACGTCCCATTGCTCTGAATCTGTGTGCAGACAAAGT	2423
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Qy	2464	GGCAACACCACCAACGTTTCGGAGTGGACCTCATCAATGAGCTTGTGGAGAACTTTGGCAG	2523
Db	2484	GGCAACACCACCAACGTTTCGGAGTGGACCTCATCAATGAGCTTGTGGAGAACTTTGGCAG	2543
Qy	2524	ATGTCCCAAGTGGTCTGGTCGGCAAGCCTTTGTCTTTGTCTGCCAGACTGTCATTGAGGA	2583
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Qy	2584	TGACTGCCTTCCCATGGACCAGTTTGCTGTGCATCTCATGCCGCATCTGCTAACCTTAGC	2643

Db	2604	TGACTGCCTTCCCATGGACCAGTTTGCTGTGCATCTCATGCCCGCATCTGCTAACCTTAGC	2663
Qy	2644	AAATGACAGGGTTCTTAACGTGCGAGTGCTGCTTGCAAAGACATTAAGACAAACTCTACT	2703
Db	2664	AAATGACAGGGTTCTTAACGTGCGAGTGCTGCTTGCAAAGACATTAAGACAAACTCTACT	2723
Qy	2704	AGAAAAAGACTATTTCTTGGCCTCTGCCAGCTGCCACCAGGAGGCTGTGGAGCAGACCAT	2763
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Qy	2824	CAGTACCAAAATCTCCGAAGATGCCATGAGCACAGCGTCCTCAACCTACTAGAAGGCTTG	2883
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Qy	2884	AATCTCGGTGTCTTTTCTGCTTCCATGAGAGCCGAGGTTTCAGTGGGCATTTCGCCACGCAT	2943
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Qy	2944	GTGACCTGGGATAGCTTTTCGGGGGAGGAGAGACCTTCCTCTCCTGCGGACTTCATTGCAG	3003
Db	2964	GTGACCTGGGATAGCTTTTCGGGGGAGGAGAGACCTTCCTCTCCTGCGGACTTCATTGCAG	3023
Qy	3004	GTGCAAGTTGCCTACACCCAATACCAGGGATTTCAAGAGTCAAGAGAAAGTACAGTAAAC	3063
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Qy	3064	ACTATTATCTTATCTTGACTTTAAGGGGAAATAATTTCTCAGAGGATTATAATTGTCACC	3123
Db	3084	ACTATTATCTTATCTTGACTTTAAGGGGAAATAATTTCTCAGAGGATTATAATTGTCACC	3143
Qy	3124	GAAGCCTTAAATCCTTC - TCTTCCTGACTGAATGAACTTGAATTGGCAGAGCATT TTC	3181
Db	3144	GAAGCCTTAAATCCTTCCTGTCTTCCTGACTGAATGAACTTGAATTGGCAGAGCATT TTC	3203
Qy	3182	CTTATGGAAGGGATGAGATTCCAGAGACCTGCATTGCTTTCTCCTGGTTTTATTTAACA	3241
Db	3204	CTTATGGAAGGGATGAGATTCCAGAGACCTGCATTGCTTTCTCCTGGTTTTATTTAACA	3263
Qy	3242	ATCGACAAATGAAATTCTTACAGCCTGAAGGCAGACGTGTGCCAGATGTGAAAGAGACC	3301
Db	3264	ATCGACAAATGAAATTCTTACAGCCTGAAGGCAGACGTGTGCCAGATGTGAAAGAGACC	3323
Qy	3302	TTCAGTATCAGCCCTAACTCTTCTCTCCAGGAAGGACTTGCTGGGCTCTGTGGCCAGCT	3361
Db	3324	TTCAGTATCAGCCCTAACTCTTCTCTCCAGGAAGGACTTGCTGGGCTCTGTGGCCAGCT	3383
Qy	3362	GTCCAGCCCAGCCCTGTGTGTGAATCGTTTGTGACGTGTGCAAATGGGAAAGGAGGGGTT	3421
Db	3384	GTCCAGCCCAGCCCTGTGTGTGAATCGTTTGTGACGTGTGCAAATGGGAAAGGAGGGGTT	3443
Qy	3422	TTTACATCTCCTAAAGGACCTGATGCCAACACAAGTAGGATTGACTTAAACTCTTAAGCG	3481
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Qy	3482	CAGCATATTGCTGTACACATTTACAGAATGGTTGCTGAGTGTCTGTGTCTGATTTTTTCA	3541
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Qy	3542	TGCTGGTCATGACCTGAAGGAAATTTATTAGACGTATAATGTATGTCTGGTGTTTTTAAC	3601
Db	3564	TGCTGGTCATGACCTGAAGGAAATTTATTAGACGTATAATGTATGTCTGGTGTTTTTAAC	3623
Qy	3602	TTGATCATGATCAGCTCTGAGGTGCAACTTCTTCACATACTGTACATACCTGTGACCACT	3661
Db	3624	TTGATCATGATCAGCTCTGAGGTGCAACTTCTTCACATACTGTACATACCTGTGACCACT	3683
Qy	3662	CTTGGGAGTGCTGCAGTCTTTAATCATGCTGTTTAAACTGTTGTGGCACAAGTTCTCTTG	3721
Db	3684	CTTGGGAGTGCTGCAGTCTTTAATCATGCTGTTTAAACTGTTGTGGCACAAGTTCTCTTG	3743
Qy	3722	TCCAAATAAAATTTATTAATAAGATCTATAGAGAGAGATATATACACTTTTGATTGTTTT	3781
Db	3744	TCCAAATAAAATTTATTAATAAGATCTATAGAGAGAGATATATACACTTTTGATTGTTTT	3803
Qy	3782	CTAGATGTCTACCAATAAATGCAATTTGTGACCTGTATTAATGATTTAAA	3831
Db	3804	CTAGATGTCTACCAATAAATGCAATTTGTGACCTGTAAAAAAAAAAAAA	3853

LOCUS AF111106 3878 bp mRNA linear PRI 03-MAR-1999  
 DEFINITION Homo sapiens protein serine/threonine phosphatase 4 regulatory subunit 1 (PP4R1) mRNA, complete cds.  
 ACCESSION AF111106  
 VERSION AF111106.1 GI:4191593  
 KEYWORDS .  
 SOURCE Homo sapiens (human)  
 ORGANISM Homo sapiens  
 Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.  
 REFERENCE 1 (bases 1 to 3878)  
 AUTHORS Kloeker, S. and Wadzinski, B.E.  
 TITLE Purification and identification of a novel subunit of protein serine/threonine phosphatase 4  
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